

# ISMP Canada Safety Bulletin

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## Palliative Care at Home PART 2: ANALYSIS OF A FATAL INCIDENT

Palliative care provides symptom management and supportive care to patients living with serious or life-limiting illness.<sup>1</sup> Increasing numbers of patients choose to receive this form of care in the home.<sup>2</sup> The previous bulletin in this 2-part series (Part 1) described a multi-incident analysis of medication incidents associated with community-based palliative care across Canada. This bulletin (Part 2) describes the analysis of a fatal incident involving HYDROMORPHONE used for pain management in a palliative home care setting and shares recommendations for the safe procurement, prescription, administration, and monitoring of opioid medications provided in palliative care kits (also known as a symptom management/relief/response kits).

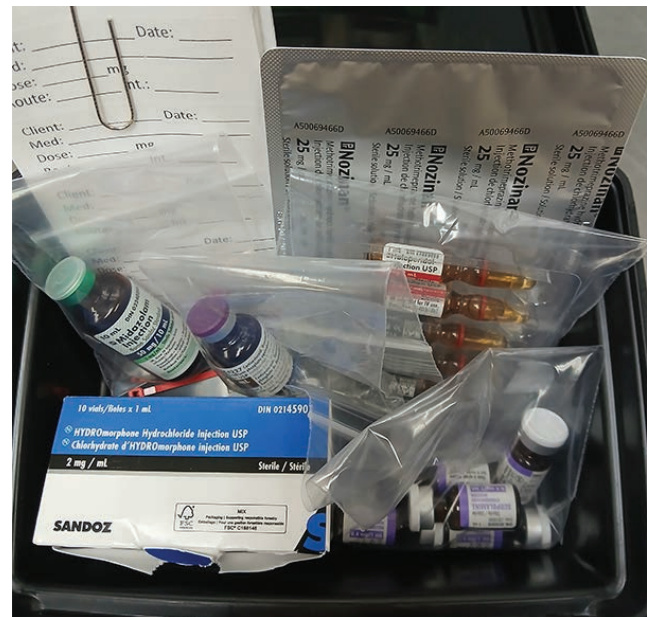
### INCIDENT DESCRIPTION

*A patient receiving palliative care in the home was given an incorrect dose of HYDROMORPHONE prepared from a symptom management kit. The prescription specified HYDROMORPHONE 1 mg subcutaneously every 1 hour as needed, but the patient received 4 doses of 10 mg each (i.e., 10 times the prescribed dose)\* over a period of about 10 hours. The incorrect dose was eventually recognized, and the patient was transferred to hospital. The patient was treated with naloxone but died several days later due to overdose and disease-related complications.*

### BACKGROUND

#### *Symptom Management Kits*

Palliative care involves a patient-centred approach that focuses on relieving pain and other distressing symptoms (e.g., nausea, anxiety, shortness of breath) to improve quality of life.<sup>4</sup> Symptom management kits (Figure 1) can be used to manage distressing symptoms in the home and minimize emergency department visits and hospitalization.



**FIGURE 1.** An example of a symptom management kit.

\* This incident is considered a pharmaceutical “never event” in hospitals: “Overdose of hydromorphone by administration of a higher-concentration solution than intended (e.g., 10 times the dosage by drawing from a 10 mg/mL solution instead of a 1 mg/mL solution, or not accounting for needed dilution/dosage adjustment).”<sup>3</sup>

Symptom management kits are currently available in multiple provinces. These kits contain preselected medications commonly required for symptom management in palliative care, for example, opioid medications for pain, haloperidol for nausea and agitation, and anticholinergic medications for excess secretions. Typical routes of administration for these medications are non-oral (e.g., injectable, sublingual, rectal). These kits are typically dispensed by a community pharmacy.

### Opioid Medications

Opioid medications are high-alert medications<sup>5</sup> commonly used in palliative care to manage moderate-to-severe pain and to relieve shortness of breath.<sup>6</sup>

In the recent multi-incident analysis of incidents associated with palliative care at home, HYDROmorphine and morphine were the medications most often reported to be involved in medication incidents.<sup>7</sup> Symptom management kits may include HYDROmorphine (at concentrations of 2 mg/mL and/or 10 mg/mL) or morphine (at concentrations of 2 mg/mL and/or 10 mg/mL and/or 15 mg/mL).

The signs and symptoms of opioid toxicity can include extreme drowsiness, dizziness, confusion, seizure-like movement, pinpoint pupils, and slowed to absent breathing.<sup>8</sup>

### INCIDENT ANALYSIS AND DISCUSSION

Figure 2 summarizes selected key factors contributing to the incident described above, according to the categories described in the Canadian Incident Analysis Framework.<sup>9</sup>

**FIGURE 2.** Selected factors contributing to a fatal incident involving HYDROmorphine used for pain management in the palliative home care setting.

**Incident:** A patient receiving palliative care in the home was given 10 times the prescribed dose of injectable HYDROmorphine from a symptom management kit.

**Outcome:** The patient was hospitalized and received naloxone at the family's request, but ultimately died from complications related to the opioid overdose and underlying disease.

#### TASK

- Volume miscalculated to be 1 mL for the prescribed 1 mg dose of HYDROmorphine (1 mg = 0.1 mL)
- The full contents of the 1 mL vial of HYDROmorphine (10 mg) was withdrawn instead of 0.1 mL (1 mg)
- HYDROmorphine dose was not independently double checked after being drawn into the syringe

#### EQUIPMENT

- Symptom management kit provided HYDROmorphine in a 10 mg vial; the prescribed dose was 1 mg
- Syringes of prepared HYDROmorphine were not labelled

#### WORK ENVIRONMENT

- Naloxone is not commonly available in the palliative home care setting

#### CARE TEAM

- Nurse did not recognize patient's symptoms as evidence of opioid toxicity
  - Symptoms of opioid toxicity overlap with symptoms of decline

#### PATIENT/FAMILY

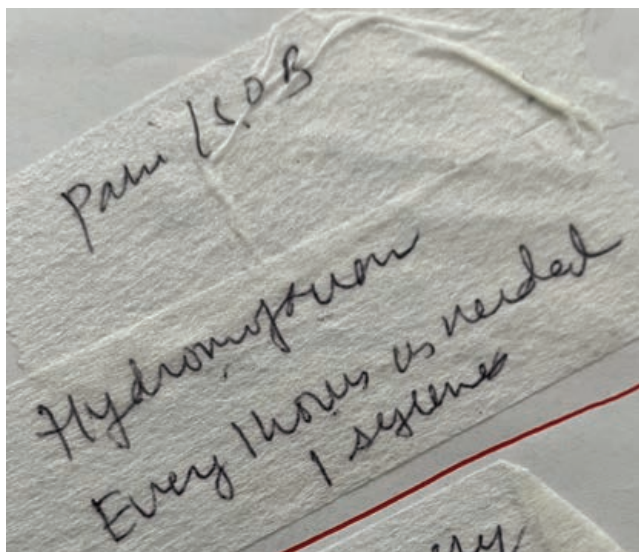
- Caregiver did not recognize patient's symptoms as evidence of opioid toxicity
  - Cognitive and psychological burden on caregivers to recognize symptoms and administer treatment at home

#### ORGANIZATION

- Limited injectable HYDROmorphine products (e.g., 1 mg/mL is not available/covered) for symptom management kits
- Lack of standardized processes to support the policy for independent double checks of high-alert medications

Analysis of this incident identified several findings that may have contributed to HYDROMORPHONE overdose.

- Limited available strengths for injectable HYDROMORPHONE (e.g., 1 mg/mL not available) in symptom management kits increased the likelihood that the patient-specific dose would be prepared incorrectly.
- Provision of a high-concentration HYDROMORPHONE product for a low dose increased the likelihood that the incorrectly calculated and prepared dose would lead to opioid toxicity.
- Lack of labelling of the prepared syringe containing HYDROMORPHONE (with labelling limited to a brief note handwritten on tape that was applied to the cup holding the prepared syringe [Figure 3]) decreased the likelihood that a dosing error would be detected.
- Lack of an independent double check of the prepared dose of HYDROMORPHONE decreased the likelihood that a dose preparation error would be detected before administration, whether by the nurse or another caregiver.



**FIGURE 3.** Image of the tape label applied to the cup into which the nurse placed the unlabelled syringe of HYDROMORPHONE for a caregiver to administer to the patient as needed for pain and/or shortness of breath (denoted as “SOB” in the image).

- Lack of standardized processes to support the policy for independent double checks of high-alert medications increased the likelihood that an independent double check would not be performed.
- Knowledge gaps related to the signs and symptoms of opioid toxicity (as compared to signs and symptoms expected with palliative decline)<sup>10</sup> decreased the likelihood that the inadvertent opioid overdose would be detected.
- Lack of a standardized protocol for making naloxone kits available in the palliative home care setting decreased the likelihood that an opioid overdose could be treated in a timely manner.

## RECOMMENDATIONS

The following system-based recommendations<sup>11</sup> for provincial/territorial health care organizations and home health care provider teams incorporate improvements suggested by the patient’s caregivers.

### **Provincial/Territorial Health Care Organizations**

- Review options for the concentrations of injectable opioid products available for symptom management kits (e.g., include HYDROMORPHONE 1 mg/mL) to allow more patient-specific doses to be available in a ready-to-administer format. This measure would minimize the need for calculations, the need for product manipulation, and the risk of preparation error at the bedside, as well as reducing medication waste.
- Include (in the kit) preprinted syringe labels with fields to satisfy all provincial requirements (which may include the medication name, concentration, dose [in mg and mL], and directions for use).
- Develop a standardized process to support the policy for independent double checks of high-alert medications (e.g., requiring documentation of independent checks after dose preparation).<sup>12</sup>
- Consider a provincial/organizational policy requiring that naloxone kits (which include an educational pamphlet for the user)<sup>13</sup> be paired with symptom management kits, in case of overdose.

- Supporting education for the caregivers at home would include instructions on how to contact the care team before administering naloxone to the patient, even in the case of accidental overdose, to aid the caregivers in making an informed decision.
- Develop a standardized opioid overdose assessment tool to help distinguish between the signs and symptoms of opioid toxicity and the signs and symptoms of natural decline. The tool could include consideration of clinical presentation, onset of symptoms in relation to opioid exposure, and response to opioid dose adjustments.<sup>10</sup>

### **Community Pharmacy Teams**

- Describe the opioid dose in mg and mL on the prescription label, to minimize the need for volume calculation (by the home care nurse, family member, or other caregiver) at the patient's bedside.
- Include (in the kit) appropriate syringes for the prescribed dose (e.g., ensure that the desired volume is visible on the syringe's gradations).
- Counsel the patient's caregiver (in person or by phone) on the dose to be administered.
- Provide a naloxone kit with symptom management kits, with training for appropriate and safe use.

### **Home Health Care Provider Teams**

- Select the lowest opioid concentration available in the standardized order set for the intended dose, to mitigate the risk of harm from dose preparation errors.
- Prepare medication doses for a caregiver to administer in an appropriate syringe for the prescribed dose and calculated volume (e.g., ensure that the desired volume is visible on the syringe's gradations).
- Label each prepared syringe in a way that does not obscure the gradations on the syringe.
- Conduct and document an independent double check for all high-alert medications<sup>12</sup> prepared in

the patient's home against the order set and pharmacy label.

- If necessary, the double check can be completed by a colleague virtually (using pictures or videos).<sup>12</sup>
- The double check may be augmented by a tertiary check from a caregiver, especially if they are expected (and trained) to administer the medication when the nurse is not present.

## **CONCLUSION**

This bulletin has identified opportunities to strengthen the safe procurement, prescription, administration, and monitoring of opioid medications provided in symptom management kits for patients receiving palliative care. Expanding product availability, requiring safeguards during medication preparation (i.e., appropriate labelling and independent double checks), and enhancing clinical knowledge to help recognize signs and symptoms of opioid toxicity, can improve medication safety in the palliative home care setting.

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